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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,033	01/04/2006	Warren Ward	WAW0101PUSA	1595

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BROOKS KUSHMAN P.C.
1000 TOWN CENTER
TWENTY-SECOND FLOOR
SOUTHFIELD, MI 48075

EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
10/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,033	WARD, WARREN	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-6,12-23 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11,24-28,30-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed September 23, 2009. Claims 1-36 are currently pending. Claims 7-11, 24-28, and 30-33, and 36 are under consideration in the instant office action. Claims 1-6, 12-23, and 34 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 29 and 35 are cancelled.

Request for continued examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/23/09 has been entered.

Withdrawn rejections

Applicant's amendments and arguments filed on 09/23/09 are acknowledged and have been fully considered. The rejections applied in the previous office action under the first and second paragraphs of 35 U.S.C. 112 for incorporating the relative term "substantially" are hereby withdrawn due to applicant's claim amendment which resulted in cancelling the term.

Maintained Rejections

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility. The instant application fails to provide adequate evidence to support the utility of the invention. Specifically, there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect. Additionally, the agents used to form the liquid impermeable but gas permeable layer (e.g. wax) are also used in the art to form controlled release formulations of drugs.

Response to Arguments

Applicant's arguments filed on September 23, 2009 have been fully considered but they are not persuasive. Applicant argues that the claimed preparation does not need to be a pharmaceutical to have utility. The examiner acknowledges that numerous inventions which are not pharmaceuticals are useful. However, applicant's claimed invention does not follow the mechanisms of drug binding to it's receptor so as to achieve therapeutic effects contrary to the currently accepted scientific principles. It is the examiner's position that a drug that is not released cannot achieve any therapeutic values even if it is administered via a device or using the commonly known dosage forms. Applicant's claimed invention is clearly analogous to taking a drug wrapped in non-biodegradable plastic that cannot get degraded inside the body. The specification does not contain sufficient evidence to support the utility of such coated substance which is not released.

Applicant also argues that the examiners selection of Cell and Molecular Biology in Rastogi as a suitable reference and instead submits a segment of Chapter 4 "Signal Transduction" in Medical Physiology by Boron et al. This is not persuasive because the examiner finds no scientific inconsistencies between the relevant portions of the two text books.

The examiner also acknowledges that cells can sense and respond to external signals. However, there is no evidence to suggest that the external signals referred to by Boron et al. are or are similar to a coated medically efficacious substance which is not released. There is no evidence to suggest that the body's response to other external signals such as mechanical stress, light, and temperature share any relation to applicant's description of the manner in which the instantly claimed preparation would interact with receptors in the body. Therefore, the examiner respectfully disagrees with applicant that the instantly claimed invention is supported by what is known in the field. While cell signaling may occur based on electrical signals in addition to chemical messengers, the applicant has submitted no evidence for a signaling phenomenon involving water molecules adjacent to a medically efficacious substance despite the fact that the said substance is coated. Additionally, the examiner finds no support in either the specification or in the scientific literature to support the applicant's assertion that water molecules are adjacent to the medically efficacious substance through the gas permeable liquid impermeable coating.

Applicant also argues that the patent office is not a functional equivalent to the FDA, therefore, the patent office has no role to study the medical feasibility or efficacy of a claimed invention. This is not persuasive because while applicant is correct that the Patent Office and the Food and Drug Administration are different agencies, the Patent Office does evaluate applicant's disclosure in light of current science applying the correct statutory guidelines in the instant case 35 U.S.C. 101. If a utility is not obvious from what is already known in the field, the specification must contain adequate evidence to support a credible, specific, and substantial utility. Given the nature of the instant claims, the specification is inadequate to support such a credible, specific, and substantial utility.

Applicant also argues that the utility of Equiwinner patches has been established via its commercial success. This is not persuasive because the commercial success of a product has no bearing for overcoming a rejection under 35 USC 101. Commercial success is one of many other mechanisms to overcome a rejection under 35 USC 103. Moreover, applicant has not adequately established that the scope of the claims is concurrent with the instant claims. The examiner reminds applicant that the burden is shifted to applicant to substantiate the utility of this particular invention commensurate with the nature and scope of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 7-11, 24-28, 30-33, and 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. The specification does not reasonably provide enablement for how to use the claimed preparation or composition for the treatment of diseases. Applicant does not provide adequate evidence to substantiate the fact that a drug coated such that the drug that is prevented from release is surly effective. Applicant provides no evidence to substantiate the assertion that a drug which is not released is effective at treating any diseases.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims

The breadth of the claim is a medically efficacious substance which is coated with a liquid impermeable but gas permeable layer such that the medically efficacious substance is prevented from release.

Nature of the invention

The nature of the invention is directed to the treatment of blocked or malfunctioning exocrine glands using a medically efficacious substance coated in a liquid impermeable but gas permeable layer.

Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area possess M.D. and/or Ph.D. in a scientific discipline such as

medicinal chemistry, biochemistry, pharmacology, biology, organic synthetic chemistry or the like.

State of, or the amount of knowledge in, the prior art

The art teaches the coating of drugs or other medically efficacious substances for controlling the release of the drug. Coated drugs are well known and include, e.g., aspirin (US patent 4508702, abstract); applicant teaches the use of coated aspirin in example 3 in the specification. The prior art does not recognize the treatment of diseases with drugs which are never released.

Level or degree of predictability, or a lack thereof, in the art

Currently, there are well established methods of coating drugs. Specifically, the use of polymers, ceramics and waxes including natural wax and beeswax for coating drugs are known in the art (US Patent No 5827538, see the whole document). However, even drugs coated with polymers, ceramics and waxes including natural wax and beeswax are designed for the controlled release of the encapsulated drug. No prior art, however, teaches a coated drug which is not released upon administration. Moreover, there is no prior art that predicts that such a drug which is not released would be efficacious.

Presence or absence of working examples

The specification fails to provide scientific data and working examples with respect to the effectiveness of the coated drugs which are not released. The information provided in the examples does not meet the currently accepted scientific standards for determining the efficacy of new pharmaceutical compositions. The currently accepted practice uses double blind controls in which one group receives the new drug and a control group receives a placebo; neither group

knows whether it receives a placebo or the new drug being tested. The examples given in the specification do not have control groups. Moreover, patients know when they are receiving the ActivSignal form versus the standard form of the drug. Additionally, the agitation of coated medically efficacious substances in acidic or alkaline water is inadequate to justify the assertion that the coating is impermeable to liquids generally. It is also inadequate to ensure that the medically efficacious substance is not released upon administration to the subject since acidic and basic water do not adequately simulate all biological fluids that might be encountered by the coated medically efficacious substance upon administration to a subject. Moreover, applicant fails to specify the acid or base used and the pH of the resulting solution.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the composition of the instant application is not released and moreover to determine whether a drug which is not released is effective.

Response to Arguments

Applicant's arguments filed on September 23, 2009 have been fully considered but they are not persuasive. Applicant argues that the 2003 Nobel lecture by MacKinnon enables the instantly claimed invention. This is not persuasive because the phenomenon described by MacKinnon is regarding hydrated ions not ionic crystals coated with beeswax. Regardless of the terminology originally used by the applicant to describe the water molecules which are adjacent to the medically efficacious substance through the gas permeable liquid impermeable coating,

applicant has attempted to relate his invention to the Nobel lecture of MacKinnon. MacKinnon does discuss the pattern of water molecules around an ion and how that relates to the interactions of this hydrated ion with receptors not patterns of water molecules on crystal drugs coated with for example with bees wax hardened with talc.

Applicant argues that the instantly claimed preparation in the form of a tablet would have a continuous thread of water molecules between the ions in the tablet and the body cells when the tablet is ingested. This is not persuasive because there is no structural evidence to support applicant's theory of such a thread of water molecules. Moreover, there is no reason to believe that such a thread of water molecules would be recognized by the body as adjacent ions. The pattern of water molecules surrounding a hydrated ion as described MacKinnon and the thread of water molecules which applicant describes are not analogous. Applying the above reasoning to other medically efficacious substances still maintains the same flaws. The formation of salicylic acid or sodium salicylate does not address the issues with the incapacity of body cells to recognize the medically efficacious substance via a thread of water molecules from within the coated tablet. Although aspirin get hydrolyzed in the body for it to be active, for the drug to be active still the active form of the drug must bind to the receptor of the drug.

The rejection of claims 7-11, 24-28, 30-33, and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The examiner was unable to ascertain the meets and bounds of the claimed invention because as written the claims are vague and indefinite. Even if applicant amended the claims the general scope of the invention is still unclear. The claim language recite a preparation for use as

a medicament, wherein the agent is prevented from release and dependant claims also recite known pharmaceutical forms such as a tablet, a capsule etc. It is not clear whether the instantly claimed invention is pharmaceutical formulation since it is prevented from being released. The claims as written, therefore, are unsearchable. Therefore, the examiner still did not apply any art in the rejection of the claimed invention.

Conclusion

Claims 7-11, 24-28, 30-33, and 36 are rejected. Claims 1-6, 12-23, and 34 remain withdrawn. Claims 29 and 35 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 9/30/09
/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616